SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K**043080**

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. HMS Coagulation System Cartridges and Controls, K042070
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for the addition of a bi-level, Heparin Dose Response (HDR) Control set.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, sample requirements, methodology, and performance.

Comparison of Predicate to Current Device

Name	HMS Controls K894317	HR ACT Control K894317	HDR Controls
Indication for use	The controls are used to verify the performance of the appropriate cartridge on the HMS Plus instrument	Same	Same
Raw Material	Plasma and Heparin	Sheep ROB and Plasma	Sheep Plasma
Diluent	DI Water	DI Water	Hexadimethrine Bromide Solution
Instrument	HMS and HMS Plus	Same	Same
Cartridge	HPT	HMS HR-ACT	HDR
Pass/Fail Criteria	Clot Time Cutoff + channel detect	Clot time range	Clot time ratio range
Storage Temp	2-10ºC	Same	Same
Rehydration Time	3 minutes	2 minutes	3 minutes
Reconstitution stability	2 hours at 2-25ºC	2 hours at 15-25ºC	1 hour at 15-25ºc
Storage Type	Lyophilized	Same	Same

5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis

b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
c) A declaration of conformity with design controls. The declaration of conformity should include:
   i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
   ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

6. A **Truthful and Accurate Statement**, a **510(k) Summary** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

_____ 12-2-2004
(Reviewer's Signature) (Date)

Comments

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